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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/669,082	09/25/2000	Richard L. Scopp	6734.US.01	3368

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EXAMINER	
DO, PENSEE T	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 08/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/669,082	SCOPP ET AL.	
	Examiner	Art Unit	
	Pensee T. Do	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-17 and 26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2, 4-17, 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry & Claims Status

The amendment filed on April 7, 2006 has been acknowledged and entered.

Claims 1-2, 4-17, 26 are pending.

Withdrawn Rejection

Rejection under 112, 1st paragraph is withdrawn herein.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 6-9, 11, 14-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Ullman et al. (US 5,536,644).

Ullman teaches a method of separating a substance from a liquid medium. The method comprises combining the liquid medium containing the substance with magnetic particles under conditions for non-specific binding of the magnetic particles. The medium thereafter is subjected to a magnetic field. The non-specific binding is achieved by means of a polycationic reagent such as a polybrene or polylysine (see abstract; col. 11, line 49). The mixture of sample plasma and Rh positive test cells stained with squarate dye was incubated; ferrofluid and polybrene were sequentially added and separation of test cells occurred in the presence of a magnetic field. (see example 2).

The ferrofluid or magnetic fluid is defined as a colloidal suspension of magnetic particles in a liquid carrier. (see col. 11, lines 12-16). Ullman also teaches that the analytes are hormones, proteins etc. (see col. 4, line 30-col. 6, line 52). Regarding claim 6, Ullman teaches an assay for thyroid stimulating hormone in example 8. Ullman also teaching using paramagnetic particles (see col. 9, line 57). Regarding claim 15, Ullman teaches a method of assaying thyroid stimulating hormone comprising forming a first complex of serum/plasma sample with paramagnetic particles coated with anti-B TSH antibody and an unconjugated polycation such as polybrene; magnetic separation; adding a label such as a fluorescer that has a chemiluminescent substance (see col.8, line 15-17); and measuring the chemiluminescence. (see example 8).

Claims 1, 7-9, 11, 15, 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Vorpahl et al. (US 5,071,774).

Vorpahl teaches a method for determining the presence of a specific binding member bound to a first particle in a liquid medium. The method comprises the method of: removing plasma from blood to be tested by mixing blood with ferrofluid, LISS and polybrene (unconjugated); applying a magnetic field to such mixture to separate the cell-free plasma which was removed and tested against three different sets of stained reagent red blood cells. For reach test, cells, and plasma was mixed on the latex sheet. Ferrofluid , polybrene and LISS were then added and the cells magnetically separated. (see col. 12, lines 38-51). Vorpahl also teaches that the specific binding members are antibody-antigen, cells having surface antigen and antibody that binds to such antigen; (see col. 2, line 58-63), hormones and receptors (see col. 3, lines 35-45).

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 7-9, 11, 15, 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Butz (US 6,017,721).

Butz teaches a method of contacting the test sample and the ligand. The sample of patient's serum is contacted with an immobilized antibodies (assay is performed with solid phase). In addition, polybrene can be added to increase reactivity. (see col. 6, lines 5-35). After incubation, the unbound test sample can be separated from the bound immobilized antibodies by magnetic separation (using magnetic particles). (see col. 6, line 55).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2, 4, 5, 10, 12, 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ullman (US 5,536,644).

Ullman has been discussed above for the teaching the claimed invention except that the large polycation has a molecular weight of 3,000 daltons or greater; a molecular weight ranging between 5,200 and 11,200 Daltons or a polylysine with a MW of 8,800 daltons.

It would have been obvious to one having ordinary skills in the art at the time the invention was made to use polycation with molecular weight within the claimed ranges or values, since it has been held where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges or an optimum value of a result effective variable involves only routine skills in the art. In re Aller, 105 USPQ 233 and In re Boesch, 617 F. 2d 272, 205, USPQ 215 (CCPA 1980).

Claims 2 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vorpahl or Butz.

Vorpahl and Butz have been discussed above for teaching the claimed invention except for the molecular weight of the polybrene of 3,000 daltons or greater.

It would have been obvious to one having ordinary skills in the art at the time the invention was made to use polycation with molecular weight of 3,000 daltons or greater, since it has been held where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skills in the art. In re Aller, 105 USPQ 233.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ullman in view of Cantor (US 5,994,085).

Ullman has been discussed above.

However, Ullman fails to teach a method of detecting free prostate specific antigen.

Cantor teaches a method for detecting free prostate specific antigen (fPSA) comprising pretreating the sample to remove complex PSA and then assaying the fPSA

by a sandwich immunoassay using two antibodies. The first antibody is specific for fPSA and is affixed on a solid phase such as a bead (see col. 3, line 32). The secondary antibody is specific for another epitope of the fPSA and contains a signal component that can be measured such as a fluorescer, luminescent molecule etc. (col. 4, lines 46-47; col. 2, line 55-col. 3, line 10).

It would have been obvious to one of ordinary skills in the art to detect free PSA using the anti-tPSA antibodies disclosed by Cantor in the method of Ullman. One skilled in the art would have reasonable expectation of success in using the method Ullman to detect free PSA because Ullman also teach using a sandwich assay and the assay of Ullman would be more sensitive because of the use of a polycation to reduce non-specific binding.

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ullman in view of Allard (US 6,107,049).

Ullman has been discussed above.

However, Ullman fails to teach detecting of total PSA (prostate specific antigen).

Allard teaches two-site immunoassay for determining total PSA or tPSA wherein two anti-PSA antibodies are employed. One of the anti-PSA antibodies is labeled (detection antibody) and the other antibody (capture antibody) is immobilized on a solid phase. The capture and detection antibodies are contacted simultaneously or sequentially with the test sample. Sequential method can be accomplished by incubating the capture antibody with the sample and adding the detection antibody; the capture antibody is separated from the liquid test mixture, and the label is measured.

Label used in the detection antibody can be selected for any of those known conventionally in the art. Commonly used labels are enzyme or a chemiluminescent moiety, a fluorophor or a radioisotope. The solid phase can be magnetic particles, latex particles etc. (see col. 6, line 64-col. 7, line 45).

It would have been obvious to one of ordinary skills in the art to detect total PSA using the anti-PSA antibodies disclosed by Allard in the method of Ullman. One skilled in the art would have reasonable expectation of success in using the method Ullman to detect total PSA because Ullman also teach using a sandwich assay and the assay of Ullman would be more sensitive because of the use of a polycation to reduce non-specific binding.

Remarks

Although the claims were indicated allowable in the previous office action, an updated search has been performed and relevant references have been found. Therefore, the Office apologizes for any inconveniences this may have caused Applicants.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 571-272-0819. The examiner can normally be reached on Monday-Friday, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Pensee T. Do
Patent Examiner
August 17, 2006

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